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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,856	07/25/2001	David H. Mack	003848.00091	4786

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EXAMINER

MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/911,856	<b>Applicant(s)</b> MACK, DAVID H.	
	<b>Examiner</b> Channing S. Mahatan	<b>Art Unit</b> 1631	

-- Th **MAILING DATE** of this communication appears on th cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-107 is/are pending in the application.
- 4a) Of the above claim(s) 10-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 106 and 107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                       |                                                                             |
|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                      | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) <u>3 Sheets</u> | 6) <input checked="" type="checkbox"/> Other: <u>Attachment for PTO-948</u> |

## **DETAILED ACTION**

### *APPLICANT'S ELECTION*

Applicant's election of Group I (Claims 1-9, 106, and 107; directed to a method of mapping) in Paper No. 10, filed 16 October 2002, is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03). Claims 10-105 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are claims 1-9, 106, and 107.

### *OBJECTION BY DRAFTSMAN*

Applicant is hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification applicant is required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

### *SEQUENCE COMPLIANCE*

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a) (1) and (a) (2). This application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 due to the

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sequences as in the specification on pages 61 and 62, lines 6 and 11, respectively, and no submission of the following items. Therefore, applicant is required to submit the following:

1. As a separate part of the disclosure on paper copy or compact disk copy, a "Sequence Listing" as 37 C.F.R. § 1.821(c).
2. A copy of the "Sequence Listing" in computer readable form as required by 37 C.F.R. § 1.821 (e).
3. A statement that the content of the paper and computer readable copies are the same and include no new matter, as required by 37 C.F.R. § 1.821 (f) and 37 C.F.R. § 1.821 (g).
4. Each sequence in the specification is required to have a SEQ ID NO. therewith.

Applicant is given the same response time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance requirement. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this office action.

#### **Claims Rejected Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C.

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1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

#### *LACK OF ENABLEMENT*

Claim 1 (lines 3-8) and all claims dependent therefrom recites the steps of “detecting and comparing the expression of at least 5 genes in said biological samples; generating a cluster map for said genes according to the correlation in expression among said genes; and analyzing said cluster map to generate gene network causal models defining regulatory relationships among said genes” which is not enabled and thus failing to provide guidance to practice. The specification on page 38-40 lists general/broad concepts applicable to the claimed invention steps of comparing the expression of genes (i.e. 5) in a biological sample, generating a cluster map based on correlation of expression, and the generation of gene network causal models (i.e. LISREL). However, absent are specific procedures and/or steps for said specific steps, particularly how and to what is gene expression compared; 2) how the cluster map is generated; 3) what is and how to determine correlation of expression; and 4) how gene network causal models are generated. Thus, the specification provides only a starting point for the direction of future research and provides no disclosure as to the specific steps of performing the claimed invention. Further, the

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method as claimed requires the “analysis of said cluster map to generate gene network causal models defining regulatory relationships among said genes”, however absent are any procedural steps for such an analysis step. Additionally, no such gene network causal models are generated from the experimental work in the specification (pages 42-63) and therefore would require undue experimentation for such performance. An individual skilled in the art would not understand how to perform the above steps unless some type of specific procedure is set forth.

### **Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

#### *VAGUE AND INDEFINITE*

Claim 2 (line 2) recites the phrase “measuring the relative and/or absolute amount of transcript of said genes” which is vague and indefinite. Applicant can resolve this issue by particularly pointing out the limitations to which “relative” encompasses. Further, it is unclear what the measured amount of gene transcript is “relative” to. Clarification of the metes and bounds, via clearer claim language, is required.

#### *LACK OF ANTECEDENT BASIS*

Claim 5 recites the limitation “said cells” on line 2. There is a lack of antecedent basis for this limitation in claim 1 from which claim 5 depends to.

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*OBJECTION TO DISCLOSURE*

The disclosure is objected to because of the following informalities:

The description of the Figures 10 and 11 (page 6-7 of the Specification) does not reference all of the subparts of the figures submitted.

The specification refers to Fig. 3A on page 58, line 28 of the specification; however, no Fig. 3A appears to be present in the disclosure.

The specification refers to Fig. 3B on page 59, lines 1, 3, and 4 of the specification; however, no Fig. 3B appears to be present in the disclosure.

The specification refers to Table 4 on page 61, line 28 of the specification; however, no Table 4 appears to be present in the disclosure.

The disclosure contains embedded hyperlinks and/or other forms of browser-executable code on pages 43, line 9 and page 47, line 4. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. A suggested format for such citation, for example, is "World Wide Web Address: ncbi.nlm.nih.gov". See M.P.E.P. § 608.01 and 608.01(p).

*INFORMATION DISCLOSURE STATEMENT*

References were lined through in the Information Disclosure Statement, Paper No. 5, filed 25 July 2001, because said references appear in duplicate (Refer to Information Disclosure Statement, Paper No. 6, filed 02 April 2002).

**Appropriate Correction Is Required.**

**No Claims Are Allowed.**

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*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *December 26, 2002*

Examiner Initials: *CSM*

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER  
GROUP 1800  
*Ad 1631*